

K960949

510(k) Premarket Notification
ProSys™ Bedside Drainage Bag (Sterile)

APR 19 1996

ITEM 8: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The purpose of this 510(k) Premarket Notification is to request clearance to market ProSys™ Bedside Drainage Bag (Sterile). ProSys™ Bedside Drainage Bag (Sterile) is available with a 2000 ml volume capacity. Each sterile bag is fitted with a permanently welded 55 inch inlet tube containing a universal connector which connects to an indwelling or external catheter. The Bedside Drainage Bag (Sterile) has a T-tap drainage valve. The inlet tube contains an anti-reflux valve to reduce the risk of urine backflow and infection and, a sample port used for urine sampling is integrated into the universal connector.

ProSys™ Bedside Drainage Bag (Sterile) is substantially equivalent to Bard® Urinary Drainage Bag with Anti-reflux Chamber. Both devices are indicated for use in the collection of free flowing urinary drainage. Both devices function in the same manner: they collect and contain urine.

The components of ProSys™ Bedside Drainage Bag (Sterile) have been subjected to extensive biocompatibility testing with results which demonstrate that the components are acceptable for use. All testing indicates that the components are non-irritating, non-sensitizing and non-cytotoxic.

Process validation testing performed on ProSys™ Bedside Drainage Bag (Sterile) included tests for resistance to bursting, resistance to impact, and for leakage. Additionally, the anti-reflux valve, tensile strength and outline weld integrity were also tested. All components performed at an acceptable level and the test results appear in Item 5a.

A comparison of the indication for use, the components, functions and characteristics of ProSys™ Bedside Drainage Bag (Sterile) and the Bard® Urinary Drainage Bag with Anti-reflux Chamber indicates that these products are substantially equivalent.

ProSys™
Bard®Dispoz-A-Bag®
Flip-Flo™

-Trademark of E. R. Squibb & Sons, Inc.
-Registered Trademark of C.R. Bard, Inc.
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